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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,296	11/12/2003	Thomas A. Dobbins	632898-044	5769
27805	7590	05/17/2006	EXAMINER	
THOMPSON HINE L.L.P.			KRISHNAN, GANAPATHY	
P.O. BOX 8801			ART UNIT	
DAYTON, OH 45401-8801			PAPER NUMBER	

1623

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,296	DOBBINS, THOMAS A.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Jul 15, 04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-10 and 27-29 in the reply filed on 2/21/2006 is acknowledged. The traversal is on the ground(s) that Groups I and II are related as combination and subcombination and the sub combination (Group I) constitutes the essential features of the combination (Group II) and hence the groups are not distinct. Based on the arguments advanced by the applicants and a perusal of the restriction requirement the Examiner has decided to examine the claims of both Groups I and II, claims 1-29.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 15-19 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (b) recites, "solids enriched in genistin" and recites further, "and comprise glycosides of genistin and daidzin". Do applicants mean solids enriched in both genistin and daidzin? Clarification is needed. A similar recitation is seen in claim 15 step (iv).

Claims that depend from a base claim this unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waggle et al (US 5,919,921).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 27-29 are drawn to a process of purifying glycosides of genistin and daidzin from impurities present in a soy isoflavone concentrate comprising digesting the concentrate with an acidic solution and separating the insoluble solids enriched in genistin and daidzin glycosides from the acidic solution. Claims 11-26 are drawn to a process of preparing the aglycones of genistin and daidzin by converting the glycosides obtained above to aglycones.

Waggle et al, drawn to isoflavones, teach the separation of glucoside enriched material from a cake of isoflavone enriched material. The process involves digesting an aqueous solution (similar to the concentrate as instantly claimed) with an acid. To improve the efficacy of the

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extraction the process is performed between 32 and 55°C. The soy material is also extracted with solvents like alcohols and water mixture to extract substantial amounts of the isoflavones (col. 4, lines 17-52; col. 5, lines 26-41; col. 6, lines 1-59). The isoflavones rich material is separated from the rest of the material by filtration (col. 5, lines 49-56). The acids that are suitable for the digestion are acetic, sulfuric, phosphoric, hydrochloric or any other suitable acid (col. 4, lines 42-44). The isoflavones obtained by this process comprise Genistin, daidzin and glycerin family (col. 11-12, Table 1).

Waggle also teaches the conversion of the isoflavones glycosides obtained in his process to the corresponding aglycones by enzymatic hydrolysis. The pH range for the said conversion is from about 3 to about 9 (col. 7, line 40 through col. 8, line 67), which means that the conversion can be performed at both acidic and basic pH ranges. The conversion can be performed at a temperature range of 5 to about 75°C (col. 9, lines 9-11).

However, Waggle does not specifically teach that his process of obtaining the isoflavones glycosides is a process for purification and also does not specifically teach the isolation/purification of a concentrate comprising genistin and daidzin. But one of ordinary skill in the art on reading the teachings of Waggle will recognize that the process steps recited by Waggle could also serve as a purification step since initial extraction using an extractant like alcohol and alcohol/water mixture extracts substantial amounts of the isoflavones glycosides. The solution obtained after this initial extraction is also similar to a concentrate. Moreover, Waggle's process yields glycosides of the genistin, daidzin and glycerin family. One of ordinary skill in the art will recognize that even though Waggle's process yields glycosides of isoflavones other than those of genistin, daidzin and glycerin, the same process will yield the glycosides of

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genistin, daidzin and glycerin if used to purify a concentrate that contains the glycosides of the three isoflavones.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the process of the prior art in a process of purifying glycosides of genistin and daidzin from impurities present in a soy isoflavone concentrate and also in a process of preparing the aglycones of genistin and daidzin by converting the glycosides obtained to aglycones, as instantly claimed with a reasonable amount of success since the essential process steps for the same are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to do so since the process of Waggle is art tested for purifying the isoflavones glycosides and converting them to the aglycones. Similarity in process steps and function entails motivation to claim the process for purifying the isoflavones glycosides and converting them to the aglycones as instantly claimed.

It is well within the purview of one of ordinary skill in the art to adjust process parameters, concentrations of reagents, repetition of steps, substituting different acids and bases in the process, etc., as a routine optimization.

Conclusion

Claims 1-29 are rejected

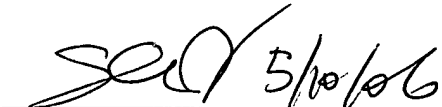
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK


Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623